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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,209	11/16/2001	Nigel Dunn-Coleman	GC648-2	6062

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GENENCOR INTERNATIONAL, INC.
ATTENTION: LEGAL DEPARTMENT
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EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/991,209	Applicant(s) DUNN-COLEMAN ET AL.	
	Examiner Russell Kallis	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 16,17,20-22,24,26,34-56 and 58-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15,18-19,23,25,27-33 and 74 is/are rejected.
- 7) ☒ Claim(s) 8,23 and 74 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 July 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9/9/2002</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-15, 18-19, 23, 25, 27-33, and 74 are examined. Claims 16-17, 20-22, 24, 26, 34-56 and 58-73 are withdrawn.

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-33 and 74 and invention B, Claims 18-19 and 57, in the paper filed 11/03/2003 is acknowledged. The traversal is on the ground(s) that an examination of the entire application can be made without serious burden to the Examiner. This is not found persuasive because in the instant case the methods of controlling the levels of phenolic acids in the cell walls of plants of Group II can be achieved using other polynucleotides that degrade the cell wall or by using direct application of chemical treatments of plant cell wall tissue, and therefore the inventions of Groups I and II are distinct and require different searches.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claims 74 and 23 are objected to because of the following informalities: Claim 74 depends from non-elected Claim 34 and Claim 23 depends from non-elected Claim 22.

Claim 8 does not further limit the process of Claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-15, 18-19, 23, 25, 27-33, and 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant broadly claims a transgenic plant comprising a ferulic acid esterase.

Applicant describes a polynucleotide of SEQ ID NO: 1 encoding a ferulic acid esterase from *Aspergillus niger*.

Applicant does not describe any other polynucleotides encoding a ferulic acid esterase.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences encoding a ferulic acid esterase. Applicants only describe a single cDNA (SEQ ID NO:1). Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for a ferulic acid esterase activity, it remains unclear what features identify a ferulic acid esterase

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encoding polynucleotide. Since the genus of a ferulic acid esterase encoding polynucleotides has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Claims 1-15, 18-19, 23, 25, 27-33 and 74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transgenic *Festuca* and *Lolium* comprising a polynucleotide encoding an FAE1 enzyme from *Aspergillus* wherein expression of the *Aspergillus* FAE1 is targeted to the vacuole, ER, or apoplast, does not reasonably provide enablement for any plant comprising any FAE1 encoding polynucleotide from any organism. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant broadly claims a plant comprising a ferulic acid esterase encoding polynucleotide linked to a vacuolar targeting sequence, further comprising a xylanase encoding polynucleotide.

Applicant teaches transformation of *Festuca* and *Lolium* with a polynucleotide encoding an FAE1 enzyme from *Aspergillus*, wherein expression of the *Aspergillus* FAE1 is targeted to the vacuole, ER, or apoplast (Examples 3-5, pages 38-40).

Applicant does not teach any plant comprising any ferulic acid esterase encoding polynucleotide other than *Festuca* and *Lolium* comprising the *Aspergillus* FAE1 encoding polynucleotide.

The unpredictability in identifying a ferulic acid esterase encoding polynucleotide is illustrated in experiments where a polynucleotide believed to encode a ferulic acid esterase showed no activity towards an esterified ferulic acid (Kroon P. *et al.* Biochemical Society

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Transactions, 1998; Vol. 26; page S167, column 2, second paragraph). Although the ferulic acid esterase encoding polynucleotide isolated from *Aspergillus niger* showed activity for ferulic acid esterified to C5 of arabinofuranose found in cereals and grasses but showed no activity towards ferulic acid esterified to the C2 and C6 residues of arabinofuranse and galactopyranose residues respectively, typical of esterified ferulic acid found in sugar beet.

Given the unpredictability in the art as to which ferulic acid esterase encoding polynucleotides would have activity upon a conjugated ferulic acid substrate associated with a particular plant species; the breadth of the claims encompassing any ferulic acid esterase encoding polynucleotide; the lack of guidance in the examples of the specification or in the prior art; undue trial and error experimentation would be needed by one skilled in the art to make and clone a multitude of non-exemplified ferulic acid esterase encoding polynucleotides and would require one of skill in the art to test in a myriad of non-exemplified plants for an altered phenotype in a multitude of non-exemplified transformed plant species. Therefore, the invention is not enabled for the scope set forth in the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-7, 15, 18-19, 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claims 2, 15 and 18, “derived” is indefinite. It is unclear what has been changed and what has been preserved in the derivation.

In Claim 13, it is unclear how the polynucleotide targets expression when the expression product is a polypeptide. The claim should read --a polynucleotide sequence that encodes a polypeptide that targets expression of the product of the ferulic acid esterase encoding polynucleotide--.

In Claim 14, “the N-terminus” typically refers to the amino end of a polypeptide. The claim is drawn to a polynucleotide. The ends of polynucleotides are referred to as the 5’ and 3’ ends.

In Claim 19, line 1; for proper antecedence, “senescence gene” should be changed to --signal sequence--.

In Claim 25 “the C-terminus” is typically used to refer to polypeptides; i.e. the carboxy terminus. The claim is drawn to a polynucleotide. The ends of polynucleotides are referred to as the 5’ and 3’ ends.

In Claims 27 and 28, “the polynucleotide sequence” refers back to “the polynucleotide sequence” of Claim 25 that refers back to “the polynucleotide sequence” of Claim 13 which is a target sequence. It is unclear how “the polynucleotide sequence” could be both a target sequence and the claimed stop codon or extension/linker sequences of Claims 27 or 28 respectively.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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Claims 1-2, 8 and 23 are rejected under 35 U.S.C. 102(a) as being anticipated by Michelson B. *et al.* U.S. Patent 6,143,543 issued November 7, 2000.

Michelson teaches a polynucleotide encoding a ferulic acid esterase (FAE III) from *Aspergillus niger* in columns 8-9 and methods of plant transformation in columns 16-17 and 21-22, wherein a plant comprising an expression cassette comprising a ferulic acid esterase encoding polynucleotide in plants derived from *Aspergillus niger*, operably linked to a promoter, is taught as an embodiment of the invention and wherein the the release of ferulic acid and diferulate dimers from grass cell walls (columns 27-28) inherently teaches the sequence of the targeting sequence from *Aspergillus niger* ferulic acid esterase (also page 16 of specification) and thus the reference teaches all the limitations of Claims 1-2, 8 and 23.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 8-13, 23, 25, 27-29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson *et al.* U.S. Patent 6,143,543 issued November 7, 2000 in view of Bartolome B. *et al.*, Applied and Environmental Microbiology; January 1997, pages 208-212; see page 208, columns 1 and 2.

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Applicant broadly claims a plant comprising both a ferulic acid esterase encoding and xylanase encoding polynucleotides linked to an ER retention signal (KDEL) and either an inducible, senescence, heat shock, or constitutive promoter.

The teachings of Michelson are discussed supra.

Michelson does not teach a polynucleotide encoding a xylanase.

Bartolome teaches recombinant expression cassettes comprising XylD and XylA (page 208, column 2 in Materials and Methods) and that a xylanase in combination with a ferulic acid esterase from *Aspergillus niger*, together more effectively released ferulic acid from the cell walls of barley and wheat cell walls than either enzyme alone (see page 208, columns 1 and 2).

It would have been obvious at the time of Applicant's invention to modify the invention of Michelson to include an expression cassette comprising a polynucleotide sequence encoding a xylanase, operably linked to a promoter. One of skill in the art would have been motivated by the teachings of Michelson of the genetic engineering of plants to express a ferulic acid esterase encoding polynucleotide and motivated by the success of Bartolome in enhancing the release of ferulic acid from cell walls of wheat and barley by a ferulic acid esterase in concert with a xylanase made from recombinant expression cassettes, and that one would have had a reasonable expectation of success of expressing the ferulic acid esterase and xylanase encoding genes in transformed plants; wherein using either an inducible, senescence, heat shock, or constitutive promoter, a KDEL ER retention sequence, and a stop codon are obvious optimizations of design parameters and by Applicant's own teachings in the specification that inducible, senescence, heat shock, and constitutive promoters, the KDEL ER retention sequence, and termination sequences are well known in the art (see specification pages 19-21).

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Claims 1-2, 8 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson *et al.* U.S. Patent 6,143,543 issued November 7, 2000 in view of Nichols S.E. *et al.* U.S. Patent issued March 3, 1998.

Applicant broadly claims a transgenic plant comprising a ferulic acid esterase encoding polynucleotide linked to a vacuolar targeting sequence.

The teachings of Michelson are discussed *supra*.

Michelson does not teach a polynucleotide encoding a vacuolar targeted signal sequence.

Nichols teaches vacuolar signal sequences and amyloplastic signal sequences for directing an enzyme into the vacuole or amyloplast of a transformed plant (column 5, lines 54-67).

It would have been obvious at the time of Applicant's invention to modify the invention of Michelson to include the vacuolar targeting sequences taught by Nichols. One of skill in the art would have been motivated by the teachings of Michelson of the genetic engineering of plants to express a ferulic acid esterase encoding polynucleotide and motivated by the teachings of Nichols that enzymes can be targeted to the vacuoles of transformed plants, and that one would have had a reasonable expectation of success of targeting the ferulic acid esterase taught by Michelson using the vacuolar targeting sequence taught by Nichols.

All claims are rejected.

Claims 3-7, 18-19, 30, and 32-33 are deemed free of the prior art.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

Russell Kallis Ph.D.
January 14, 2004

A handwritten signature in black ink, appearing to read "Amy Nelson", with a stylized flourish at the end.

**AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**